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Section XII: 510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990
510(k) Summary

MAR 1 2 2009

NAME OF FIRM: U.S. Implant Solutions, LLC
650 South Central Avenue,
Suite 1000
Oviedo, FL 32765

510(k) FIRM CONTACT: Scott Garrett
President
U.S. Implants

TRADE NAME: CompresSURE Fracture Repair System

COMMON NAME: Cannulated Fixation Bone Screw with Washer, Bolt Nut

CLASSIFICATION: Smooth or threaded metallic bone fixation fastener (*see 21CFR, Sec. 888.3040)*

Single/multiple component metallic bone fixation appliances and accessories (*see 21 CFR, Sec. 888.3030*)

DEVICE PRODUCT CODE: HWC

SUBSEQUENT PRODUCT CODE: HTN

SUBSTANTIALLY EQUIVALENT DEVICES:
Zimmer 878 Barr Bolt **(Pre-amendment)**
Linvatec Corp. Washer, Bolt, Nut, Orthopedic **(K954682)**
Biomet Cannulated Screw System **(K024086)**
Osteonics Osteo 4.0 Cannulated Screw System **(K983165)**
Synthes 4.5mm Cannulated Screw **(K963172)**

DEVICE DESCRIPTION: The U.S. Implants CompresSURE Fracture Repair System is a fracture fixation screw, washer, nut-and-bolt system for cortical wall compression of a bone fracture across the fracture site and, as well, provides an alternative to a cancellous bone screw for fracture fixation in the ankle, knee - proximal tibia, distal femoral, patella, etc.. The screw/bolt and nut is cannulated for use over a 1.6mm guide pin allowing for accurate placement of the screw/nut assembly in conjuction with use of fluoroscopic image x-ray. A full range of sizes are available from 25mm to 67mm in 3mm increments. The screw/bolt, washers, and nut are manufactured from High Strength 6-4 ELI Titanium Alloy with an Anodized surface. Cannulated drills, countersinks, depth gauge, and driver instruments are available for use in insertion of the screw, washer, bolt-and-nut system. Removal (when necessary) of the device is carried out percutaneously. Pull-out and bending strength testing according to ASTM F543 & F1264 show over 2 times the strength to conventional standard 4.0mm cannulated cancellous screws.

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510(k) Summary Continued:

INTENDED USE:

Indications for use is where the CompresSURE is indicated for fracture fixation where fracture compression is desired, and where insertion of the nut-and-bolt system does not increase the risk of morbidity due to the need for surgical access to both sides of the compressed area. The device may also be used when compression between separate bones is desired (i.e.- the syndesmosis) as long as there is not increased morbidity associated with the insertion of a nut-and-bolt system, as discussed above.

The system is not intended for spinal use.

BASIS OF SUBSTANTIAL EQUIVALENCY:

The U.S. Implants CompresSURE Fracture Repair System is substantially equivalent to a Pre-amendment device from Zimmer. Also SE to the Linvatec, Biomet, Synthes, and Osteonics (now Stryker) Cannulated Screw Systems.

SUMMARY OF SAFETY AND EFFECTIVENESS:

The U.S. Implants CompresSURE Fracture Repair System is shown to be safe and effective for use in fracture fixation in small and large bone and small and large bone fragments where precision placement is required.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 12 2009

US Implant Solutions, LLC
% Mr. Scott Garrett
650 South Central Avenue, Suite 1000
Oviedo, FL 32765

Re: K081813
Trade/Device Name: CompresSURE Fracture Repair System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC, HTN
Dated: March 2, 2009
Received: March 4, 2009

Dear Mr. Garrett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) NUMBER: K081813

DEVICE NAME: **CompresSURE Fracture Repair System**

INDICATIONS FOR USE:

The CompresSURE System is indicated for fracture fixation where fracture compression is desired, and where insertion of the nut-and-bolt system does not increase the risk of morbidity due to the need for surgical access to both sides of the compressed area. The device may also be used when compression between separate bones is desired (i.e.- the syndesmosis) as long as there is not increased morbidity associated with the insertion of a nut-and-bolt system, as discussed above.

The system is not intended for spinal use.

Prescription Use X AND/OR Over-The-Counter-Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number _____

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